

# Supplement to Quality System Certificate

No. SUP 044904 0055 Rev. 02

This supplement is **Q5 044904 0046 Rev. 03**  
only valid in  
conjunction with the  
main certificate:

**Certificate Holder:** **B. Braun Medical Inc.**  
824 Twelfth Avenue  
Bethlehem PA 18018  
USA

**Facility(ies):** **B. Braun US Device Manufacturing LLC**  
901 Marcon Boulevard, Allentown PA 18109-9341, USA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 + A1:2019 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014 + A1:2019)"

**Audit Report:** 72198429  
**Dated:** 2024-08-19

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

**Valid from:** 2024-09-05



Christoph Dicks  
Head of Certification/Notified Body